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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,522	12/13/1999	CHET M. CRUMP	041861-01500	1246

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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary

Application No.

09/459,522

Applicant(s)

CRUMP ET AL.

Examiner

Darwin P. Erez

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Terminal Disclaimer

2. The terminal disclaimer filed on 7/08/2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,227,200 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-17,19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,343,857 to Schneider et al.

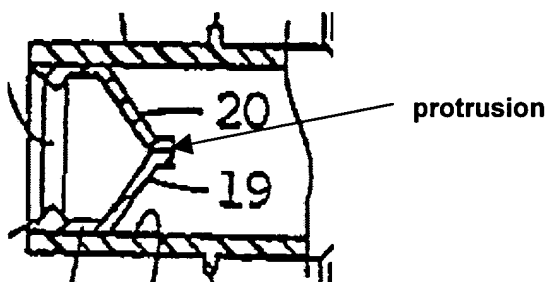
1. **As to claim 1**, Schneider teaches an apparatus comprising:

a catheter **23**;

a manifold **10,11** defining a ventilation circuit disposed in communication with the catheter to be advanced through the ventilation circuit of the manifold and into the respiratory tract of the patient; and

Art Unit: 3761

a valve **16** disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit and for at least partially occluding the distal end of the catheter, the valve being capable to frictionally engage the distal end (see Fig. 4), wherein the valve comprises at least one protrusion (see attached Figure) on at least one surface of the valve; and wherein the valve is a flap **20**.



2. **As to claim 2**, Schneider discloses a valve comprising a flap **20** movable between a first, distal position (see Fig. 4), and a second, proximal position (see Fig. 2).
3. **As to claim 3**, Schneider teaches the flap having a protrusion engaging the catheter.
4. **As to claim 4**, Schneider teaches a catch **19** to engage the flap as is drawn into the second, proximal position, and to retain the flap in the second position (member **19** engages flap **20**, as seen in Fig. 2, and retains flap **20** in the closed, second position).
5. **As to claim 5**, Schneider teaches a flap **20** that is pivotably connected to the manifold.
6. **As to claim 6**, Schneider teaches a valve having a flap that is generally disk-shaped because the valve is located within port **15**, which is circular.

Art Unit: 3761

7. **As to claim 7**, Schneider teaches a valve having an open position (as seen in Fig. 4) and a closed position (as seen in Fig. 2) wherein friction maintains the valve in the closed position.
8. **As to claim 8**, Schneider teaches a valve comprising an aperture (as seen in Figure 4, where the catheter **23** passes through) and the flap disposed to selectively cover the aperture.
9. **As to claim 9**, Schneider teaches a collar **33** disposed in the manifold having an aperture.
10. **As to claim 10**, Schneider teaches the collar including a port **33** for injecting liquid.
11. **As to claim 11**, Schneider teaches an endotracheal catheter system comprising:
 - a catheter **23** having a distal end;
 - a ventilator manifold **10** disposed in communication with the catheter such that the catheter may be advanced through the manifold into the respiratory system of the patient and withdrawn from the respiratory system of the patient through the manifold; and
 - a valve **16** for at least partially occluding the distal end of the catheter (see Fig. 4), the valve being configured to frictionally engage the distal end and thereby occlude the distal end wherein the valve comprises a flap **20** and wherein the valve further comprises at least one protrusion (see attached Figure) on at least one surface of the valve.

12. **As to claim 12**, Schneider teaches a flap **20** configured to engage the distal end of the catheter via the protrusion (see Fig. 4).
13. **As to claim 13**, Schneider teaches a first wiper seal **24** and a second wiper seal **27** disposed about the catheter when the catheter is advanced in the manifold.
14. **As to claim 14**, Schneider teaches a system wherein the catheter is retractable so that the distal end of the catheter is disposed proximally from the first wiper seal and distally from the second wiper seal.
15. **As to claim 15**, Schneider teaches a respiratory suction apparatus comprising:
 - a suction catheter **23** having distal end;
 - a protective sleeve **22** surrounding the catheter;
 - a manifold **10,11** connected to the protective sleeve and having means for accommodating inspiration and expiration of respiratory gases **13,14**; and
 - a valve **16** connected to the manifold and pivotally moveable with respect thereto for engaging the distal end of the catheter to minimize the amount of air being drawn thereinto responsive to suction through the catheter wherein the valve comprises a flap **20** and wherein the valve further comprises at least one protrusion (see attached figure) on a surface of the valve.
16. **As to claim 16**, Schneider teaches a valve comprising a pivotable flap **20**.
17. **As to claim 17**, Schneider teaches a valve comprising an aperture (as seen in Figure 4, where the catheter **23** passes through).
18. **As to claims 19 and 20**, Schneider teaches a locking member **19** disposed in communication with the flap **20** for selectively preventing movement of the flap (as seen

in Fig. 2, member **19** engages flap **20** and prevents further movement inwardly) and wherein the locking member comprises a projection extending inwardly.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al in view of US 6,168,758 to Forsberg et al.

21. **As to claims 22-25**, Schneider fails to specifically teach the type of material the valve is constructed of.

Forsberg et al. discloses a liquid assay device comprising a valve composed of polyether block amides (col. 6, lines 38-49).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any well known material, including the polyether block amides of Forsberg et al. or the recited limitations of the claims, because it is a mere substitution of one valve material for another. Also, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of choice. *Sinclair & Carroll Co. V. Interchemical Corp.*, 327, 65 USPQ 297 (1945) also note *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Allowable Subject Matter

22. Claim 18 is allowed over the prior art of record.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on (703) 308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Art Unit: 3761

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe
August 20, 2002



Aaron J. Lewis
Primary Examiner